

Instead, such discussed differences merely help the Examiner appreciate important claim distinctions discussed thereafter.

The various embodiments of the invention relate to a diagnostic ultrasonic imaging system and method for producing a three-dimensional, harmonically generated image. Although diagnostic ultrasound *harmonic* imaging systems are known and although diagnostic *three-dimensional* ultrasound imaging systems are known, a diagnostic ultrasound imaging system providing *three-dimensional, harmonically generated images* has never been created for a variety reasons. Applicants are also the first to realize that such three-dimensional images could be obtained from moving ultrasound reflectors as well as stationary ultrasound reflectors to generate a three-dimensional Doppler image using harmonic imaging techniques.

According to other embodiments of the disclosed invention, the three-dimensional image is generated from signals having different frequencies corresponding to the different depths of the ultrasound reflectors from which the signals are reflected. For example, the ultrasound signals used to create the three-dimensional ultrasound image may predominantly be based on ultrasound reflections at the harmonic frequency for shallower depths and at the fundamental frequency for deeper depths.

In still other embodiments of the disclosed invention, the ultrasound imaging system uses a Doppler processor coupled to an image processor so that the three-dimensional image corresponds to ultrasound reflections from moving ultrasound reflectors. As a result, the ultrasound imaging system provides a harmonically generated, three-dimensional Doppler image.

The sole reference cited by the Examiner is the patent to Ishibashi *et al.*, which discloses a total of eight different embodiments of therapeutic ultrasound thermotherapy systems for heating malignant tumors. The systems also include components for imaging tissues based on reflections from ultrasound transmitted by an imaging transducer at a first frequency that is separate from a therapy transducer transmitting the therapeutic ultrasound at a second frequency. In some embodiments, the first frequency is a harmonic of the second frequency. However, as discussed in greater detail below, none of the disclosed embodiments include an ultrasound transducer that transmits ultrasound at a fundamental frequency and receives ultrasound echoes

at a harmonic frequency, and processes the received harmonic echoes to provide a three-dimensional image.

The patent Ishibashi *et al.* does not disclose or suggest a diagnostic ultrasound imaging system for providing ultrasound images that are both three-dimensional and harmonically generated. The Examiner has pointed out a number of places in which the Ishibashi *et al.* patent purportedly discloses a diagnostic ultrasound imaging system that produces harmonically generated three-dimensional images. As discussed in detail below, a closer study of the Ishibashi *et al.* patent indicates that it does not disclose the subject matter attributed to it. For example, the Examiner acknowledges in line for all of page 4 of the Office Action that Ishibashi *et al.* discloses a "mode B operation col. 11, line 60-column 12 line 58." As the Examiner will appreciate, this mode of operation is not a mode that generates a three-dimensional image. Page 4 of the Office Action further states that the filter shown in Figure 2 and described in line is 34-49 of column 11 passes signals at "f2 which are a harmonic of the fundamental f1 (col. 10 lines 4-5 vs. col. 10 line 6-col. 11 line 4, or as supplemented by the italicized statement below)...." However, the embodiment shown in Figure 2 does not perform any harmonic imaging. Instead, the embodiment of Figure 2 is, in fact, a block diagram of a portion of Figure 1. With reference to Figure 1, a pulse generator 12 generates pulse signals at the frequency f1, and a continuous wave generator 11 generates a continuous signal at the frequency f1. A switch 13 couples either the continuous wave generator circuit 11 or the pulse generator 12 to a therapeutic transducer 2. With further reference to Figure 1, a synchronization circuit 18 includes a pulse generator that generates signal pulses at a second frequency f2. (*See*, col. 10, lines 61-66). The pulsed signals at the second frequency f2 are applied to the imaging probe 16. Received echoes signals at the second frequency f2 are applied through various circuits to B-mode processing unit 22 for display on a CRT 29. (*See*, column 11, lines 4-26). Is therefore apparent that the portion of the Ishibashi *et al.* patent referred to by the Examiner describes a system in which therapeutic ultrasound is transmitted by a therapy transducer at the first frequency f1 and imaging ultrasound is transmitted and received by an imaging transducer at the second frequency f2. Since the frequency of the ultrasound echoes used to produce the image is the same as the frequency of the transmitted ultrasound, the embodiment in Figures 1 and 2 does not provide harmonic imaging.

The Examiner also refers to the Ishibashi *et al.* embodiment shown in Figure 7. However, the embodiment of Figure 7 is actually a portion of the embodiment shown in Figure 6. The embodiment of Figure 6, like the embodiment of Figure 2, transmits therapeutic ultrasound at a frequency of f_1 and transmits an ultrasound signal for diagnostic imaging at a frequency of f_2 . Although the ultrasound transmitted by the diagnostic transducer may be at a frequency f_2 that is a harmonic of the frequency f_1 of the ultrasound transmitted by the therapeutic transducer, the disclosed system nevertheless generates an image based on ultrasound echoes at the same frequency f_2 as the ultrasound transmitted by the diagnostic transducer. This is apparent from the statement in col. 14, lines 36-38 "the time of generating ultrasonic waves for ultrasonic imaging from the probe 16 are adjusted..." Although the portion of col. 15 cited by the Examiner indicates the B-mode image is generated using echoes at a frequency f_2 that is a harmonic of the frequency f_1 transmitted by the therapeutic transducer, the echoes at the frequency f_2 are echoes of ultrasound transmitted at the same frequency f_2 . Significantly, the frequency f_2 of the echoes used to generate the ultrasound image is not a harmonic of the frequency f_2 transmitted to generate the ultrasound echoes used to form an image.

The Examiner also refers to other portions of the Ishibashi *et al.* patent that disclose other embodiments generating an image, including a three-dimensional image, from ultrasound echoes at the harmonic frequency. However, these other systems are simply variations of the systems shown in Figure 6. Like the embodiment shown in Figure 6, the images generated using ultrasound echoes at the harmonic frequency f_2 are echoes of ultrasound transmitted at a frequency f_2 that is a harmonic of the frequency f_1 of the therapeutic ultrasound. In no instance does the Ishibashi *et al.* patent teach or suggest transmitting ultrasound at a frequency of f_1 and then using ultrasound echoes of the transmitted ultrasound at a frequency of f_2 to generate a three-dimensional image. In fact, it is apparent from Figures 1, 5, 6, 12, 17 and 19, which show arrows both to and from the imaging transducer 16, that the ultrasound echoes received by the imaging transducer 16 at the harmonic frequency f_2 are echoes of signals transmitted by the imaging transducer 16 at that same frequency f_2 . If, as the Examiner apparently contends, the imaging transducer 16 provided signals at the harmonic frequency f_2 corresponding to ultrasound echoes from ultrasound signals transmitted by the therapeutic transducer 2 at the fundamental frequency f_1 , there would be no reason for a transmit signal to be

applied to the imaging transducer 16 in Figures 1, 5, 6, 12, 17 and 19. In contrast to the bi-directional signal line coupled to the imaging transducer 16, the line coupled to the therapeutic transistor 2 is uni-directional, as indicated by the single arrow in Figures 1, 5, 6, 12, 17 and 19. It is therefore clear that Ishibashi *et al.* fail to disclose harmonically generating a three-dimensional image.

Even if the Ishibashi *et al.* patent could somehow be considered to suggest harmonically generating three-dimensional images, it would still fail to suggest generating such images by using ultrasound echoes at different frequencies depending upon the depth from which the ultrasound echoes are received. Furthermore, the Ishibashi *et al.* patent clearly does not disclose or suggest a harmonically generated three-dimensional ultrasound *Doppler* image.

Turning, now, to the claims, claim 28 distinguishes over Ishibashi *et al.* patent by specifying that the claimed ultrasound imaging system includes a transmitter applying a signal to an ultrasound transducer having a fundamental frequency, an ultrasound receiver coupled to the ultrasound transducer to receive ultrasound reflections from the transmitted signal, a filter coupled to the receiver to pass signals having a harmonic frequency, and an image processor coupled to the filter to generate a three-dimensional image from the harmonic signal at the output of the filter. As explained above, the Ishibashi *et al.* patent does not disclose a system in which a signal at a fundamental frequency is coupled to the imaging transducer 16, and an ultrasound signal that is a harmonic of the signal transmitted from the transducer 16 is filtered and used to generate a three-dimensional image.

Independent claimed 43 also patentably distinguishes over the Ishibashi *et al.* patent by specifying an ultrasonic imaging system having an ultrasonic transducer transmitting ultrasonic pulses having a fundamental frequency component, a beamformer receiving echoe signals and generating corresponding output signals, a filter selectively passing components of the beamformer output signals that are harmonics of the transmitted fundamental frequency component, and an image processor generating a three-dimensional image from the harmonic frequency component output from the filter.

Method claim 71 specifies generating a three-dimensional image by transmitting an ultrasound signal into the body at a fundamental frequency, detecting echoes of the transmitted ultrasound signal at a frequency that is a harmonic of the fundamental frequency, and

then using the detected echoes to form a three-dimensional image. As explained above, the Ishibashi *et al.* patent generates images using echoes of transmitted ultrasound, but the transmitted ultrasound and the ultrasound echoes have the same frequency f_2 .

Method claim 82 similarly specifies transmitting ultrasonic signals into the body having a fundamental frequency component, receiving echoes of the transmitted ultrasound that have a frequency component that is a harmonic of the fundamental frequency component, storing signals derived from the harmonic frequency component, and then displaying a three-dimensional image from the stored signals. As explained above with reference to claim 71, Ishibashi *et al.* do not teach or suggest this subject matter.

Method claim 89 distinguishes over the Ishibashi *et al.* patent for much the same reason that claim 82 does, and further because it specifies that the signals used to form a three-dimensional image are a blend of fundamental components and harmonic components. In contrast, the imaging transducer 16 used in the various Ishibashi *et al.* embodiments forms images solely from components of received echoes that have the same frequency as the transmitted ultrasound from which the echoes are generated.

Claims 103-107 are presented for provoking in interference with U.S. patent No. 5,928,151. Since these claims are identical to the claims in the '151 patent, they are presumed valid pursuant to 35 U.S.C. §282. Method claim 103 specifies transmitting ultrasonic energy at a first frequency band into a subject, receiving ultrasonic echo information, filtering from the echo information a plurality of information signals associated with a second frequency band that comprises at least a harmonic of the first frequency band, and then forming a three-dimensional reconstruction using the information signals. As explained above, the Ishibashi *et al.* patent does not disclose forming a three-dimensional image or reconstruction using information signals that are a harmonic of the ultrasonic energy transmitted into a subject. Method claims 105-107 patentably distinguish over the Ishibashi *et al.* patent for much the same reason as claim 103 and further because they specify:

- (1) obtaining a plurality of Doppler information signals from the echo information at the harmonic frequency band to allow Doppler image to be displayed (in the case of claim 105);

(2) obtaining information signals associated with both a first frequency band and a harmonic frequency band and then forming a three-dimensional reconstruction in response to the information signals to allow a composite image to be displayed in which signals in the first frequency band are used to image a far-field region and signals in the harmonic frequency band are used to image a near-field region (in the case of claim 106); and

(3) obtaining first information signals associated with a first frequency band and second information signals associated with a harmonic frequency band, compounding the first and second information signals and then forming a three-dimensional reconstruction as a function of the compounded information signals.

Clearly, the Ishibashi *et al.* does not disclose any of the additional features of these claims.

Finally, independent apparatus claim 104 is directed to an ultrasound apparatus that includes a transducer, a transmit beamformer coupled to the transducer, a receive beamformer coupled to the transducer, and a filter coupled to the receive beamformer to filter information signals associated with frequency band that is a harmonic of a transmitted fundamental frequency band. As explained above, the Ishibashi *et al.* patent does not disclose or suggest transmitting ultrasonic signals from a transducer having a first frequency and then receiving and filtering signals from the transducer having a harmonic frequency.

The claims that are dependent on the above-discussed independent claims also patentably distinguish over the Ishibashi *et al.* patent because of their dependency on patentable independent claims and because of the additional limitations added by those claims. For example, claims 30-32, 34, 35, 46-51, 76, 77, 102 and 106 further specify various aspects of forming an ultrasound image based on ultrasound echoes having different frequencies depending upon the depth from which the ultrasound echoes are obtained. As mentioned above, the Ishibashi *et al.* patent does not disclose the additional subject matter of these claims. Nor does the Ishibashi *et al.* patent disclose or suggest generating a three-dimensional *Doppler* image as specified in claims 36-38, 52-54, 78-80, 84-87, 95-97 and 105.

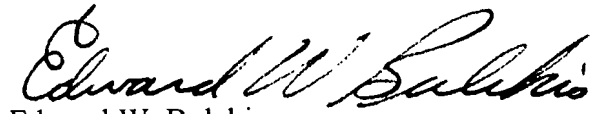
The Section 112 rejections are being obviated by amending claims 34, 72, 83 and 93 so they are no longer indefinite. None of these amendments narrow or otherwise alter the scope of the claims.

Insofar as all of the claims in the application are now in proper form and clearly allowable over the Ishibashi *et al.* patent, favorable consideration and a Notice of Allowance are earnestly solicited.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "**Version with Markings to Show Changes Made**".

Respectfully submitted,

DORSEY & WHITNEY LLP



Edward W. Bulchis

Registration No. 26,847

EWB:dms

Enclosures:

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Request for Initialed Copy of Previously Submitted Form PTO-1449

1420 Fifth Avenue, Suite 3400

Seattle, WA 98101-4010

(206) 903-8800 (telephone)

(206) 903-8820 (fax)

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